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EXAMINER	
FETTEROLF, BRANDON J	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,992	LONGENECKER, B. MICHAEL	
	Examiner	Art Unit	
	BRANDON J. FETTEROLF	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-11,13-18,20-29,31 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-11,13-18,20-29,31 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/26/2006, 6/10/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The Election filed on May 14, 2009 in response to the Restriction Requirement of 1/27/2009 has been entered. Applicant's election with partial traverse of Group I, claims 1, 3-18, 20-30, as specifically drawn to the special technical feature of a method of treating an individual with non-small cell lung cancer, comprising administering to that individual a MUC-1 formulation comprising a liposome and at least one polypeptide selected from the group consisting of SEQ ID NO: 1 and 2 has been acknowledged. Application election of the nodal stage (c) as the species has been acknowledged. While acceding to the restriction between NSCLC and prostate cancer, Applicants assert that the traversal is necessary because claim 1 is mischaracterized in that it encompasses variants of SEQ ID NO: 1 and 2, as well as, SEQ ID NO: 1 and 2 per se as stated in the restriction requirement. Moreover, Applicants assert that the claimed invention is limited to BLP25 (claims 13, 14, 18 and 19), which is not identical to Morse's BLP24. Additionally, Applicants assert that the present claims recite the limitation of treating stage IIIB locoregional NSCLC, e.g., no malignant pleural effusion, which is not taught by Morse. As such, Applicants contend that Morse's teaching of BLP24 vs. NSCLC is not decisive and in particular does not necessitate limitation to a particular SEQ ID NO:.

These arguments have been carefully considered, but are not found persuasive.

First, the Examiner acknowledges and appreciates Applicants acceding to the restriction requirement between NSCLC and prostate cancer. Secondly, the Examiner acknowledges and does not dispute Applicants contention that the present invention also encompasses variants of SEQ ID NO: 1 and/or 2. Thirdly, the Examiner acknowledges Applicant contention that BLP24 is not the same as BLP25. However, the Examiner recognizes that Morse et al. teach BLP25 and apologizes for any confusion the Examiner's previous statement regarding the teachings of Morse et al. may have evoked. Lastly, with regards to the limitation of state IIIB locoregional NSCLC, the Examiner acknowledges the current amendment which incorporates this limitation. However, as set forth below, the current claimed limitation does not appear to be a contribution over the prior art. As such, the restriction requirement is deemed to be proper and is made FINAL.

Claims 1, 3-11, 13-18, 20-29 and 31-32 are currently pending and under consideration.

Upon careful review and consideration, the species election has been withdrawn.

Information Disclosure Statement

The Information Disclosure Statement filed on 9/29/2006 and 6/10/2009 are been acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. A signed copy of the IDS is attached hereto.

Claim Objections

Claims 11 and 20 are objected to because of the following informalities: Claim 11 recites prostate cancer and determining the levels of PSA concentration. However, independent claim 1 is drawn to treating NSCLC, not prostate cancer. Accordingly, it is unclear why one would want to determine the growth rate of prostate cancer or measure PSA levels in a patient with NSCLC. . Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-11, 13-18, 20-29 and 31-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*,

83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1 and 18 recites the broad recitation "stage IIIb locoregional", and the claim also recites "without malignant pleural effusion" in parenthesis which is the narrower statement of the range/limitation. In the present case, it is unclear whether the limitation in the parenthesis is meant to further limit stage IIIb locoregional or alternatively, the limitation in the parenthesis is another name for stage IIIb locoregional NSCLC. For prior art purposes, the limitation in the parenthesis will be interpreted as being another name for stage IIIb locoregional. As such, stage IIIb locoregional will be interpreted as being the same as stage IIIb without malignant pleural effusion.

Claims 7-8 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how the patients are evaluated.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-11, 15-17 and 31-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Written Description Guidelines for examination of patent applications indicates, "the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical characteristics and/or other chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicant was in possession of the claimed genus." (Federal register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3) and (see MPEP 2164).

The claims encompass a method of treating an individual with non-small cell lung cancer stage IIIb locoregional (without malignant pleural effusion) comprising administering a MUC-1 based formulation comprising a polypeptide having the amino acid sequence of SEQ ID NO: 1, a variant of the amino acid sequence of SEQ ID NO: 1, the amino acid sequence of SEQ ID NO: 2 and a variant of the amino acid sequence of SEQ ID NO: 2. With regards to the variants, claims 31-32 further limit the variant comprising at least 5 consecutive amino acids of any of SEQ ID NOs: 1-8 or alternatively, a sequence which is at least 80% identical in amino acid sequence to any of SEQ ID NOs: 1-8. Thus, the claims encompass variants of SEQ ID NO: 1 and/or 2 which are useful for the treatment of cancer.

In the instant case, the specification teaches that a "variant" of a MUC-1 polypeptide can differ in amino acid sequence from the sequence represented in SEQ ID NO: 1 or 2 by one or more substitutions, deletions, insertions, inversions, truncations or a combination thereof. The specification discloses the reduction to practice of eight amino acid sequences from a MUC-1 core repeat (page 6 of the specification). Moreover, the specification the reduction to practice of using BLP25, e.g., SEQ ID NO: 1 for the treatment of cancer (see Examples). However, there is no teaching in the specification regarding which amino acids of SEQ ID NO: 1 and/or 2 can be substituted and/or deleted while retaining the ability of the peptide to treat cancer. Further, there does not appear to be any art-recognized correlation between any structure (other than SEQ ID NO: 1) and its activity, e.g. treat cancer, based on which those of ordinary skill in the art could predict which amino acids can vary from SEQ ID NO: 1 without losing therapeutic activity. Consequently, there is no information about which amino acids can vary from SEQ ID NO: 1 or 2 in the claimed genus of proteins and still retain its activity.

Thus, based on the knowledge and predictability in the art, those of ordinary skill in the art would not conclude that Applicants was in possession of the claimed genus of proteins based on the species of SEQ ID NO: 1 and 2.

Therefore, only MUC-1 polypeptides consisting of the amino acid sequence of SEQ ID NO: 1 and 2 which are useful for the treatment of cancer, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-5, 7-11, 13-18, 20-21, 23, 24, 25-29 and 31-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmer et al .(Clinical Lung Cancer 2001; 3 (1): 49-57) in view of Sugiura et al. (Clinical Cancer Research 1999; Vol. 3: 47-50).

Palmer et al. teach a method of treating an individual with non-small cell lung cancer stage IIIB or IV comprising: (a) selecting for treatment an individual who has small cell lung cancer stage IIIb or IV; (b) administering a priming dose of cyclophosphamide; and (c) administering to that individual an amount of a formulation comprising a liposome comprising a 20 or 200 μg of a MUC-1 lipopolypeptide referred to as BLP25, 100 mg of Lipid A and 20 mg/mL liposomal lipids (dipalmitoyl phosphatidhylcholine, cholesterol and phosphatidylglyceral) (see page 51, Treatment Plan, Page 50, Vaccine Preparation and Patient Selection). With regards to the administration, Palmer et al. teach that the formulation was administered via subcutaneous injection at weeks 0, 2, 5 and 9, as well as at 3 month intervals (page 51, 2nd column, Treatment Plan). With regards to BLP25, the reference teaches that the palmitoyl lysine residues at the carboxy terminal was included in BLP25 to enhance the incorporation of BLP25 into the liposome particle (page 50, Vaccine

Preparation). Palmer further teaches that the patients were evaluated prior to treatment to serve as a base line, during each vaccination treatment and at week 11 and 15. In particular, the reference teaches that patients were evaluated for tumor response, immune response, T-cell proliferation, survival rate of the individual and changes in the individual's quality of life (page 51, Patient Evaluation, Immunological Assays and page 53, Outcome Evaluation and paragraph bridging page 55 and 56). Lastly, the reference teaches that, as a group, patients with advanced stage NSCLC have a much shorter natural history and overall survival than patients with breast and some other cancers, which may be important considerations in explaining why some of these patients failed to demonstrate an immune response on this prolonged vaccination (page 55, 2nd column, last paragraph).

Note: BLP25 is a 25 mer comprising the amino acid sequence of STAPPAHGVTSAPDTRPAPGSTAPP, e.g., SEQ ID NO: 1, further containing Two non-muc-1 amino acids added as a scaffold for attaching the lipid tail, making it a total of 27 amino acids comprises the following amino acid sequence STAPPAHGVTSAPDTRPAPGSTAPPKG, e.g., SEQ ID NO: 2 or a variant of SEQ ID NO: 1. BLP25 has a palmitoyl group at the epsilon amino group of the C-terminal lysine giving the molecule the following structure STAPPAHGVTSAPDTRPAPGSTAPP(K-palmitoyl)G, e.g., a variant of SEQ ID NO: 2, see WO 02/43699, page 9, lines 7-12.

Palmer et al. does not specifically teach selecting patients having stage IIIB locoregional (without malignant pleural effusion) NSCLC and administering said formulation to said patient.

Sugiura et al. disclose assessing the survival times of patients with stage IIIB without effusion, stage IIIB with effusion and stage IV NSCLC. In particular, the reference teaches that survival times of stage IIIB with effusion was significantly different from that of stage IIIB without effusion, but not from that of stage IV, e.g., 15.3 months for stage IIIB without pleural effusion, 7.5 months for stage IIIB with pleural effusion and 5.5 months for stage IV (page 48, paragraph bridging 1st and 2nd column (abstract). In view of this, the reference teaches that stage IIIB patients with pleural effusion should be regarded as a separate prognostic group than stage IIIB without pleuroal effusion (page 49, 2nd column). Therefore, the reference teaches that distinguishing between stage IIIB with pleural effusion from stage IIIB without pleural effusion is necessary for treatment selection, since patients with pleural effusion cannot be treated with combined

chemotherapy and radiotherapy which are accepted as standard treatment for locally advanced NSCLC (page 50, 1st column, lines 1-5).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the reference so as to modify the method taught by Palmer et al .to select patients suffering from stage IIIB locoregional (without malignant pleural effusion) in view of the teachings of Sugiura et al. One would have been motivated to do so because as taught by Sugiura et al., stage IIIB patients with pleural effusion should be regarded as a separate prognostic group than stage IIIB without pleuroal effusion and further, survival times of stage IIIB with effusion are significantly different from that of stage IIIB without effusion, but not from that of stage IV, e.g., 15.3 months for stage IIIB without pleural effusion, 7.5 months for stage IIIB with pleural effusion and 5.5 months for stage IV. Thus, one of ordinary skill in the art would have a reasonable expectation of success that by modifying the method taught by Palmer et al .to select patients suffering from stage IIIB locoregional (without malignant pleural effusion) in view of the teachings of Sugiura et al., one would achieve a longer survival time to induce an immune response to the prolonged vaccination with BLP25.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Palmer et al .(Clinical Lung Cancer 2001; 3 (1): 49-57) in view of Sugiura et al. (Clinical Cancer Research 1999; Vol. 3: 47-50), as applied to claims 1, 3-5, 7-11, 13-18, 20-21, 23, 24, 25-29 and 31-30 above, in further view of Palmer et al. (Annals of Oncology 2000; 11 (supplement 4): page 42, Abstract 179PD, referred to herein as Palmer 2).

Palmer et al. teach a method of treating an individual with non-small cell lung cancer stage IIIB or IV comprising: (a) selecting for treatment an individual who has small cell lung cancer stage IIIb locoregional (without pleural effusion); (b) administering a priming dose of cyclophosphamide; and (c) administering to that individual an amount of a formulation comprising a liposome comprising a 20 or 200 μg of a MUC-1 lipopolypeptide referred to as BLP25 (Same as SEQ ID NO: 1, see applicants remarks to the Restriction Requirement), 100 mg of Lipid A and 20 mg/mL liposomal lipids (dipalmitoyl phosphatidhylcholine, cholesterol and phosphatidylglyceral) (see page 51, Treatment Plan, Page 50, Vaccine Preparation and Patient Selection).

Palmer et al. in view of Sugiura et al. do not explicitly teach that BLP25 was administered at a dose of 1000 μg and Lipid A is at a dose of 500 μg.

Palmer 2 teaches a phase I/II trial of BLP25 administered at a dose of 1000 μg subcutaneously weekly for 8 weeks in patients with metastatic stage IIIB and IV non-small cell carcinoma of the lung. In particular, the abstract teaches that BLP25 in a dose of 1000 μg s/c is well tolerated and produces a dose dependent anti-MUC1 specific cellular immune response in NSCLC.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the reference so as to optimize the amount of BLP25 and Lipid A in the formulation taught by Palmer et al. in view of the teachings of Palmer 2. One would have been motivated to do so because Palmer 2 teaches that BLP25 in a dose of 1000 μg s/c is well tolerated and produces a dose dependent anti-MUC1 specific cellular immune response in NSCLC. With regards to the amount of Lipid A, the court has found that"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). As such, one of ordinary skill in the art would have a reasonable expectation of success that by optimizing the amount of BLP25 and Lipid A in the formulation taught by Palmer et al. in view of the teachings of Palmer 2., one would achieve a method of inducing an immune response.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Palmer et al .(Clinical Lung Cancer 2001; 3 (1): 49-57) in view of Sugiura et al. (Clinical Cancer Research 1999; Vol. 3: 47-50), as applied to claims 1, 3-5, 7-11, 13-18, 20-21, 23, 24, 25-29 and 31-30 above, in further view of Morse et al. (Current Opinion in Molecular Therapeutics 2001; 3: 102-105).

Palmer et al. teach a method of treating an individual with non-small cell lung cancer stage IIIB or IV comprising: (a) selecting for treatment an individual who has small cell lung cancer stage IIIb locoregional (without pleural effusion); (b) administering a priming dose of cyclophosphamide; and (c) administering to that individual an amount of a formulation comprising a liposome comprising a 20 or 200 μg of a MUC-1 lipopolypeptide referred to as BLP25 (Same as SEQ ID NO: 1, see applicants remarks to the Restriction Requirement), 100 mg of Lipid A and 20 mg/mL

liposomal lipids (dipalmitoyl phosphatidhylcholine, cholesterol and phosphatidylglyceral) (see page 51, Treatment Plan, Page 50, Vaccine Preparation and Patient Selection).

Palmer et al. in view of Sugiura et al. do not explicitly teach that the formulation comprises IL-2.

Morse et al .teach that the use of BLP-25 has been initiated in a phase IIb trial in advanced NSCLC to determine if higher or more frequent dosing would enhance its effects (page 103, 1st column, Phase II). Morse et al .further teach that the next phase of development is to administer BLP-25 in combination with liposomal IL-2, wherein the purpose of the study is to determine if the effect of BLP-25 is enhanced by IL-2 (page 103, 1st column, Phase II).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the reference so as to modify the method taught by Palmer et al. to further include IL-2 in view of the teachings of Morse et al. to determine if the effect of BLP-25 is enhanced by IL-2. Thus, the strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Sernaker, 702 F.2d 989, 994-95, 217 USPQ 1, 5-6 (Fed. Cir. 1983). Thus, one of skill in the art would have a reasonable expectation of success that by modifying the method taught by Palmer et al. to further include IL-2 in view of the teachings of Morse et al., one would achieve a method of enhancing the immune response of BLP-25.

Therefore, No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRANDON J. FETTEROLF whose telephone number is (571)272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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